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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,032	07/26/2001	Gregory M. Fahy	074066-0100	9126

20995 7590 05/12/2005

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

WARE, DEBORAH K

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/916,032

Applicant(s)

FAHY, GREGORY M.

Examiner

Deborah K. Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-45 is/are pending in the application.
- 4a) Of the above claim(s) 29, 30 and 38-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-28 and 31-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/29/03</u> . | 6) <input type="checkbox"/> Other: _____ |

pd

DETAILED ACTION

Claims 19-45 are pending.

Claims 1-18 are canceled.

This Application is a CIP of case Serial No. 09/771,221, filed January 26, 2001, which claims benefit of 60/178,157, filed January 26, 2000. The CIP has been abandoned. Applicant is requested to update the status of the CIP case at page 1, line 6, of the instantly filed specification.

Election

Applicant's election with traverse of Group I, claims 19-28 and 31-37, in the reply filed on September 25 2003 is acknowledged. The traversal is on the ground(s) that there is no undue burden to the examiner and that the same search for Group I can also be used for Group III.

This is not found persuasive because there are different method steps employed for Group III, that are not required of Group I. The methods of Group I, require the steps of preparing preservation medium, adding preservation medium, and cooling whereas, method of Group III requires preparing two protective solutions, a first protective solution and second protective solution, and then contacting each with the living system at two separate temperature ranges, a first temperature range and a second temperature range to effect the cooling steps.

Thus, two separate cooling steps are also required of Group III. Thus, the different process steps means a different search is required for Group III, which is not required of Group I, and this would present a burden on the examiner to search for

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these two separate and distinct inventions because there is two way distinctness between the two since no preparation of a preservation medium and adding of it to a living system are required. Further, two distinct and separate inventions are recognized to be classified in separate and distinct classes.

Claims 29-30 and 38-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 25, 2003.

The requirement is still deemed proper and is therefore made FINAL.

Petition

The petition filed July 21, 2003, to withdraw the abandonment letter of May 20, 2003, was received as indicated in a letter mailed to Applicant on April 13, 2004.

Miscellaneous Papers

The miscellaneous letter filed December 4, 2003, was also received.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on September 29, 2003, was received. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Amendment

The amendment filed June 20, 2002, has been received and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. The double patenting rejection was removed because

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the rejection was moot in light of the abandonment of the copending case serial no.

09/771, 221, as noted above.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-24, 31-34 and 36-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 20-24 are not clearly described in the instantly filed specification for tonicity in ranges of 1 to 4 times isotonic, 1.1 to 2.7 times isotonic, 1.1 to 2 times isotonic, 1.1 to 1.5 times isotonic, and 1.2 to 1.5 times isotonic. Further, the cryoprotective agents as well as antinucleating polymers: polyvinyl pyrrolidone having a mean molecular mass of 5000 daltons, polyethylene glycol having a mean molecular mass of 1000 daltons, polyvinyl alcohol-polyvinyl acetate copolymer, and its total concentration of 0.1 to 0.7 times isotonic as well as acetol are not clearly described in the specification. Although these limitations of the claims are supported in the original claims is acknowledged, it is suggested that they be described in the specification.

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Claims 19-28 and 31-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Response to Arguments

Applicant's amendment of June 20, 2002, has removed the prior rejections under this statute, 35 USC 112, second paragraph but in review of the specification once again by the examiner it is deemed that "living system" has not been adequately defined with respect to its intended meaning and thus, the new rejection is presented herein below:

The claims 19-28 and 31-37 are rendered vague and indefinite for the recitation of the term "living system" since it is unclear what is meant by the term because it is not well defined in the instant specification. The metes and bounds of the claims can not be determined. The term in and of itself may read on a whole animal or human being per se. Further, the language "wherein the tonicity is from ___ to ___ times isotonic" as recited in each of claims 20, 21, 22, 23 and 24 renders the claims indefinite since it is unclear whether the recitation is intended to mean that the tonicity is greater than the effective osmotic concentration, or whether it means it's the same as the intracellular concentration. The metes and bounds of the claims can not be determined, therefore.

Claim Rejections - 35 USC § 103

Response to Arguments

Applicant's arguments, see pages 7-9, filed June 20, 2002, with respect to the previously applied 103 rejection have been fully considered and are persuasive. The

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previous rejection of the claims has been withdrawn. However, new art has been discovered in view of the newly submitted claimed subject matter and applied herein as follows:

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 19 and 31-36 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over newly cited Fahy et al. (US Patent No. 6,616,858) as cited on enclosed PTO-892 Form (A).

Claims are drawn to methods for reducing or eliminating cooling injury in a living system comprising: preparing a preservation medium having a tonicity which is sufficiently hypertonic to minimize cooling injury, wherein the medium comprises a

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carrier solution and cryoprotective agent. The agent can be dimethyl sulfoxide (DMSO), formamide, and ethylene glycol. Also it can comprise antinucleating polymers such as polyglycerol and polyvinyl alcohol-polyvinyl acetate copolymer in combination at a total concentration of 0.1 to 0.7 times isotonic. The polyethylene glycol can have a mean molecular mass of 1000 daltons. The carrier solution can also comprise polyvinyl pyrrolidone having a mean molecular mass of 5000 daltons. In addition the method includes adding the medium to the living system and cooling the living system to a temperature below 0 °C.

Fahy et al ('858) teach methods for reducing or eliminating cooling injury in a living system comprising: preparing a preservation medium to minimize cooling injury, wherein the medium comprises a carrier solution and cryoprotective agent. Note the abstract and Figures 3-4, column 1, lines 10-12 and column 5, lines 1-6. The agent can be dimethyl sulfoxide (DMSO) (see column 9, line 38), formamide (see column 9, line 39), and ethylene glycol (see column 11, line 57). Also it can comprise antinucleating polymers such as polyglycerol (see abstract and column 11, line 3) and polyvinyl alcohol-polyvinyl acetate copolymer (see the abstract) in combination at a total concentration of 0.1 to 0.7 times isotonic (see column 16, lines 66-67). The polyethylene glycol can have a mean molecular mass of 1000 daltons (see column 12, line 34). The carrier solution can also comprise polyvinyl pyrrolidone having a mean molecular mass of 5000 daltons (see column 14, lines 42-43). In addition the method includes adding the medium to the living system and cooling the living system to a temperature below 0 °C (see column 15, lines 27-28 and Figure 4).

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The claims appear to be identical to the cited disclosure and are, therefore, considered to be anticipated by the teachings of the cited reference. The steps of preparing a preservation medium, adding it to a living system, and cooling a living system are disclosed; and its having a tonicity which is sufficiently hypertonic to minimize cooling injury is inherent to the medium of Fahy et al ('858). The identical ingredients are in the preservation medium disclosed by Fahy et al, and provide the same function which is minimal injury to a living system. The tonicity of Fahy et al ('858) is inherently sufficiently hypertonic to minimize cooling injury by the presence of these ingredients since Fahy et al disclose the identical preservation medium which includes these ingredients.

However, in the alternative that there is some unidentified claim characteristic for which provides for a difference between the claims and Fahy et al ('858), then such difference is considered to be so slight as to render the claims prima facie obvious over the cited reference.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a preservation medium having tonicity which is sufficiently hypertonic to minimize cooling injury via the preservation medium comprising the disclosed ingredients, adding it to a living system, and cooling the living system as disclosed by Fahy et al.

Clearly one of skill would have expected successful results for minimizing cooling injury as Fahy et al teach the same. The same ingredients to prepare the preservation medium are disclosed by Fahy et al and the same successful result of minimizing

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cooling injury is achieved upon adding it to a living system, and then cooling the living system. The steps of preparing a preservation medium, and adding it to a living system and cooling the living system are clearly disclosed.

One of skill would have been motivated to select for these ingredients as disclosed by Fahy et al. The medium would have at least been expected to be successful and sufficiently hypertonic to minimize cooling injury. In the absence of persuasive evidence to the contrary the claims are alternatively rendered *prima facie* obvious.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fahy et al ('858 as noted above) in view of newly cited Fahy et al (US Patent No. 6,395,467), as cited on enclosed PTO-892 Form (B).

Claim 37 is drawn to a cropprotective agent which further comprises acetol.

Fahy et al ('858 noted above) is discussed above.

Fahy et al (US Patent No. 6,395,467) teach acetol at column 19, line 58.

The claim 37 differs from Fahy et al ('858) since acetol is not disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine with the preservation medium of Fahy et al ('858) with the acetol disclosed by Fahy et al ('467) to carry out the method for reducing cooling injury in a living system. Acetol is clearly disclosed at Table 4, column 19, line 58, and one of skill would have expected successful results of selecting for acetol based upon this teaching wherein it clearly forms a superior carrier solution. Therefore, one of skill would have been motivated to select for acetol. Thus, in the absence of persuasive

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evidence to the contrary the claim is rendered prima facie obvious over the cited prior art.

Claims 20-28 are rendered free of the prior art.

Claims 19 and 31-37 fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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DEBORAH K. WARE
PATENT EXAMINER
Deborah K. Ware
May 9, 2005